

Philip Morris Products S.A.	Confidential
2024 PMSS Report: <i>IQOS</i> devices & <i>HeatSticks</i>	Page 1 of 10
Annex 1: MRTP Use Behavior and Consumer Understanding and Perception	Version 1.0

Annex 1:

MRTP Use Behavior and Consumer Understanding and Perception

FDA STNs	Tobacco Product Names
MR0000059	<i>Marlboro Amber HeatSticks</i>
MR0000060	<i>Marlboro Green Menthol HeatSticks</i>
MR0000061	<i>Marlboro Blue Menthol HeatSticks</i>
MR0000133	<i>IQOS System Holder and Charger</i>
MR0000192	<i>IQOS 3 System Holder and Charger</i>
Tobacco Product Category	HTP
Tobacco Product Sub-category	open HTP and HTP consumable
Applicant	Philip Morris Products S.A. (PMP S.A.)
Date of Report	April 28, 2024
Reporting Period	March 1, 2023, to February 29, 2024

Confidentiality Statement

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris Products S.A.

Philip Morris Products S.A.	Confidential
2024 PMSS Report: <i>IQOS</i> devices & <i>HeatSticks</i>	Page 2 of 10
Annex 1: MRTP Use Behavior and Consumer Understanding and Perception	Version 1.0

TABLE OF CONTENTS

1. SUMMARY – MRTP USE BEHAVIOR AND CONSUMER UNDERSTANDING AND PERCEPTION 3

2. *IQOS* MRTP POSTMARKET STUDIES AND ANALYSES UPDATE 3

3. ADULT PREVALENCE AND PRODUCT USE PATTERNS..... 7

3.1. Prevalence..... 7

3.2. Product Use Patterns..... 7

4. ADULT CONSUMER UNDERSTANDING AND PERCEPTION 7

5. CONCLUSIONS – MRTP USE BEHAVIOR AND CONSUMER UNDERSTANDING AND PERCEPTION 10

6. ANNEXES..... 10

LIST OF TABLES

Table 1: Summary and Status of *IQOS* MRTP U.S. Postmarket Surveillance Studies..... 4

Table 2: UTUS 2022 to 2023 Estimates: Awareness, Ever Use, and Past 30-Day Use of *IQOS*..... 9

Confidentiality Statement

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris Products S.A.

Philip Morris Products S.A.	Confidential
2024 PMSS Report: <i>IQOS</i> devices & <i>HeatSticks</i>	Page 3 of 10
Annex 1: MRTP Use Behavior and Consumer Understanding and Perception	Version 1.0

1. SUMMARY – MRTP USE BEHAVIOR AND CONSUMER UNDERSTANDING AND PERCEPTION

The *IQOS* system has not been marketed or distributed in the U.S. since the removal of *IQOS* products from the market on November 29th, 2021.¹ There remains some evidence of use in the U.S.; but it is unknown how these *IQOS* users acquire *HeatSticks*.

2. *IQOS* MRTP POSTMARKET STUDIES AND ANALYSES UPDATE

During this reporting period, Estimation of Prevalence of *IQOS* Use among Adults and Estimation of Awareness and Use of *IQOS* among Underage Individuals studies were implemented as planned albeit without oversampling in the geographic regions *IQOS* had once been sold (Charlotte, NC; Atlanta, GA; and Richmond, VA) in the Underage Tobacco Use Survey (UTUS).

As documented in a letter to the FDA Office of Compliance and Enforcement on November 9th, 2021,² the International Trade Commission (ITC) issued a decision that halted the importation of *IQOS* products into the United States. As of November 29, 2021, Philip Morris USA (PM USA) was no longer marketing or selling *IQOS* products in the U.S., which hindered our ability to study and surveil *IQOS* use. This led to a pause in both *IQOS* Cross-Sectional PACS and *IQOS* Cohort PACS study conduct and ended reporting from the U.S. *IQOS* Owners Panel.³

The current status of our postmarket studies and analyses is presented in [Table 1](#): . Please note that, aside from reporting from our ongoing survey studies such as the Underage Tobacco Use Survey (UTUS) and the Adult Tobacco Consumer Tracking study (ATCT), we do not plan to conduct other postmarket studies in 2024.

¹ In September 2021, the International Trade Commission (ITC) issued an order imposing an importation ban on the *IQOS* device and Marlboro *HeatSticks* into the U.S., and a cease and desist order on the marketing and sale of product already imported into the U.S.

² Letter to Ann L. Simoneau, Director, Office of Compliance and Enforcement, Center for Tobacco Products, on November 9th, 2021 from Altria Client Services LLC, on behalf of Philip Morris USA

³ On January 14, 2022, Philip Morris Products S.A. submitted the *Premarket Tobacco Product Application Amendment and General Correspondence Submission* to LCDR Michael Gu regarding the *Adjustment to the Postmarket Surveillance and Studies (PMSS) Plan for MR0000059 - MR000061 and MR0000133*.

Confidentiality Statement

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris Products S.A.

Philip Morris Products S.A.	Confidential
2024 PMSS Report: <i>IQOS</i> devices & <i>HeatSticks</i>	Page 4 of 10
Annex 1: MRTP Use Behavior and Consumer Understanding and Perception	Version 1.0

Table 1: Summary and Status of *IQOS* MRTP U.S. Postmarket Surveillance Studies

Study Name	Study Details	Status
<i>IQOS</i> With Marlboro HeatSticks Cross-Sectional Postmarket Adult Consumer Study (PACS) ALCS-CMI-17-36-HT	This study is a repeated cross-sectional study of adult (21+) ever established <i>IQOS</i> users recruited from the <i>IQOS</i> consumer database. The objectives of the online survey are to 1) characterize adult ever established <i>IQOS</i> users and their tobacco use patterns; 2) characterize risk perceptions of <i>IQOS</i> ; and 3) describe initiation, complete switching from cigarette smoking to <i>IQOS</i> , transitions to/back to cigarette smoking, and quitting behaviors relevant to <i>IQOS</i> use. We plan to field the PACS annually for four years.	We plan to restart the study when <i>IQOS</i> has been available for a sufficient time in the U.S. market. We will communicate the detailed study timeline to FDA and provide an amended protocol when we have a firmer understanding of the return-to-market timing for <i>IQOS</i> .
<i>IQOS</i> with Marlboro HeatSticks Cohort Postmarket Adult Consumer Study (PACS) ALCS-CMI-17-37-HT	This study will be conducted among ~2,100 adult recent (have used <i>IQOS</i> for ≤ 6 months), current, established <i>IQOS</i> users and a reference sample of ~1,600 adult combustible cigarette smokers recruited through a mixture of sources. The objectives of this online, longitudinal cohort study are to 1) characterize tobacco product use behaviors; 2) characterize transitions (e.g., initiation, switching, transitioning to/back to cigarettes, and quitting); 3) assess self-reported health-related quality of life, signs and symptoms by product use; and 4) assess risk perceptions of <i>IQOS</i> and cigarettes among adult established <i>IQOS</i> users and cigarette smokers over time. The <i>IQOS</i> Cohort PACS involves a closed 24-month observation period, with follow-ups at 3, 6, 12, 18 and 24 months.	We plan to start the study when <i>IQOS</i> has been available for a sufficient time in the U.S. market. We will communicate the detailed study timeline to FDA and provide an amended protocol when we have a firmer understanding of the return-to-market timing for <i>IQOS</i> .

Confidentiality Statement

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris Products S.A.

Philip Morris Products S.A.	Confidential
2024 PMSS Report: <i>IQOS</i> devices & <i>HeatSticks</i>	Page 5 of 10
Annex 1: MRTP Use Behavior and Consumer Understanding and Perception	Version 1.0

Study Name	Study Details	Status
Secondary Analysis: Estimation of Prevalence of <i>IQOS</i> Use	This secondary analysis used <i>IQOS</i> relevant data drawn from ALCS' ongoing consumer research study, the Adult Tobacco Consumer Tracking Study (ATCT), among a nationally representative sample of adults in the U.S. The objectives of the secondary analyses are to estimate (1) prevalence of <i>IQOS</i> use, (2) prevalence of exclusive, dual and poly tobacco use with <i>IQOS</i> , (3) days and amount of product use among <i>IQOS</i> users and (4) initiation, quitting and complete switching behaviors relative to <i>IQOS</i> use among U.S. adults 21 years of age or older. The extent of the reported analyses depends on the number of current <i>IQOS</i> consumers identified in the ATCT dataset.	Data collection relevant to <i>IQOS</i> is ongoing. In this report, we provide a summary of ATCT data collected between March of 2023 and February of 2024. Because the prevalence of <i>IQOS</i> use in the adult general population is very low, we report only frequency counts for <i>IQOS</i> use in this report.
Reporting from the U.S. <i>IQOS</i> Owners Panel	The dynamic longitudinal <i>IQOS</i> Owners Panel tracks adult (21 years and older) tobacco consumers' use trajectories with <i>IQOS</i> over time. Using results from this study, we describe (1) <i>IQOS</i> owners' switching behavior over time, (2) the usage of <i>IQOS</i> and other tobacco products among adult <i>IQOS</i> owners, and (3) the demographic profile of adult <i>IQOS</i> owners. The information we report is consistent with the information reported in support of the <i>IQOS</i> PMTA. Outcome measures are reported in three-month intervals.	<i>IQOS</i> Owners Panel data collection ceased as of November 29th, 2021, as a result of the ITC decision and <i>IQOS</i> becoming unavailable in the U.S. market. We will notify FDA if the <i>IQOS</i> Owners Panel resumes.

Confidentiality Statement

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris Products S.A.

Philip Morris Products S.A.	Confidential
2024 PMSS Report: <i>IQOS</i> devices & <i>HeatSticks</i>	Page 6 of 10
Annex 1: MRTP Use Behavior and Consumer Understanding and Perception	Version 1.0

Study Name	Study Details	Status
Secondary Analysis: Estimation of Awareness and Use of <i>IQOS</i> among Underage Individuals	This analysis will use <i>IQOS</i> relevant data drawn from ALCS' ongoing Underage Tobacco Use Survey (UTUS), a nationally representative survey of U.S. household-dwelling individuals 13-20 years of age. The objectives of the analyses are to estimate (1) awareness of <i>IQOS</i> and (2) ever and past 30-day <i>IQOS</i> use among underage individuals, as well as to estimate (3) lifetime use behavior, and (4) past 30-day use behavior among ever and past 30-day underage <i>IQOS</i> users, respectively. Use behaviors include exclusive, dual, and poly tobacco use with <i>IQOS</i> as well as frequency of use. Some requirements of postmarket reporting necessitated modifications to the UTUS survey specific to <i>IQOS</i> and adjustments to the sampling plan.	We stopped oversampling geographic regions (Atlanta, GA; Charlotte, NC; Richmond, VA) starting in April 2022. In this report we provide a summary of UTUS findings collected between April of 2023 and February of 2024. We will re-evaluate study methodology when we have a firmer understanding of the return-to-market timing for <i>IQOS</i> and distribution geographies. We will communicate updated plans to FDA when we have a firmer understanding of the return-to-market strategy for <i>IQOS</i> .

Confidentiality Statement

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris Products S.A.

Philip Morris Products S.A.	Confidential
2024 PMSS Report: <i>IQOS</i> devices & <i>HeatSticks</i>	Page 7 of 10
Annex 1: MRTP Use Behavior and Consumer Understanding and Perception	Version 1.0

3. ADULT PREVALENCE AND PRODUCT USE PATTERNS

3.1. Prevalence

Prevalence of adult *IQOS* use is very low, which aligns with absence of marketing and distribution in the U.S. Data from ATCT,⁴ our ongoing survey that provides a nationally representative sample of ~28,800 U.S. adults (21+) annually, revealed four reported *IQOS* past 30-day users between March 1st, 2023 to February 29th, 2024 (Annex P01-1). Data from the ATCT demonstrates low prevalence of heated tobacco product use among adults in the U.S.

3.2. Product Use Patterns

The *IQOS* Cross-Sectional (ALCS-CMI-17-36-HT), *IQOS* Owners Panel, and the *IQOS* Cohort (ALCS-CMI-17-37-HT) were not conducted during the reporting period. Additionally, as noted in the secondary analysis plan, a small sample of *IQOS* users was collected through ATCT, which precluded analysis regarding dual/poly use, amount and frequency of use, initiation, complete switching, and tobacco quitting behaviors relative to *IQOS*.

4. ADULT CONSUMER UNDERSTANDING AND PERCEPTION

No postmarketing studies were undertaken during this reporting period to capture adult consumer understanding and perception of *IQOS*. We can gain some insight on past adult perceptions and understanding of *IQOS* from the few studies that were published on the topic. One published study evaluated the effect of modified risk claims on intentions to try and risk perceptions of *IQOS* among a sample of 3,161 U.S. adult cigarette smokers (Seidenberg et al., 2024). Findings demonstrated that modified risk claim exposure led to higher willingness to try *IQOS* and lower perceived risk and exposure from completely switching to *IQOS*.⁵ Results of the UNDERAGE AWARENESS, EVER USE, AND PAST 30-DAY USE (UTUS) suggest that underage awareness, ever use, and past 30-day use of *IQOS* is very low (Annex a03). The UTUS results are based on a sample of 5,676 underage individuals in the U.S.; aggregated from quarters 2, 3, and 4 surveys conducted in 2023 and quarter 1 survey conducted in 2024. About one in five participants (n=1,103) replied they were “not sure” whether they had ever seen or heard of *IQOS* and another 8 did not reply to the question and were removed from further analysis. In the remaining sample of 4,565 participants an estimated 3.5% of youth (13-17 years) and 9.4% of young adults (18-20 years) reported having ever seen or heard of *IQOS*. An estimated 0.4% of youth and 1.3% of

⁴ PMSS: Secondary Analysis: Estimation of Prevalence of IQOS® Use

⁵ Seidenberg A, Boynton M, Brewer N et al., (2024). Effects of modified risk tobacco product claims on consumer responses. *Nicotine and Tobacco Research* 26(4): 435-443; <https://doi.org/10.1093/ntr/ntad187>

Confidentiality Statement

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris Products S.A.

Philip Morris Products S.A.	Confidential
2024 PMSS Report: <i>IQOS</i> devices & <i>HeatSticks</i>	Page 8 of 10
Annex 1: MRTP Use Behavior and Consumer Understanding and Perception	Version 1.0

young adults reported ever use of *IQOS*. Less than 0.5% of youth and young adults reported past 30-day use of *IQOS* (Table 2:).

Estimated awareness and ever use was higher among underage young adults compared to youth. Among those who had seen or heard of *IQOS* (n=255), friends/peers/classmates were the most common source of information (39.2%), followed by advertisement at gas stations, convenience stores, or other retail stores (20.1%).

Among the 27 individuals who had indicated use of *IQOS*, but not within the past 30 days (*i.e.*, *IQOS* ever-users), three correctly identified that *IQOS* “only uses sticks containing actual tobacco,” while another three did not know and one person did not respond to the question. Of the eight individuals who reported use of *IQOS* in the 30 days prior to taking the survey, three correctly identified *IQOS*. Together this evidence shows a certain level of confusion about *IQOS*, and that self-reported use may be overestimated among underage individuals.

For heated tobacco products in general, an estimated 1.0% of middle and high school students were current users of heated tobacco in 2023 based on the National Youth Tobacco Survey (NYTS) results.⁶ We consider that the estimated 1.0% of current HTP use may be an overestimate for the following reasons. First, prior research indicated a proportion of participants reporting awareness and use of HTPs when these products were in very limited distribution in the U.S. For example, based on NYTS data collected during early 2019, an estimated 1.6% of middle-school and high-school students used HTPs during the 30 days prior to the assessment.⁷ Another study conducted in 2017 showed that an estimated 9.1% of 16- to 19-year-olds were aware of *IQOS*, a HTP brand.⁸ Both studies were conducted before *IQOS* was authorized and available for sale in the U.S. in late 2019 and while other HTPs were also in very limited distribution in the U.S. Similarly, the most recent NYTS study had been conducted in the first half of 2023, well after the removal of *IQOS* products from the U.S. markets. Second, based on results from UTUS described above, very few underage individuals who indicated they had ever used or currently use the product were able to identify *IQOS* correctly. Moreover, since NYTS began to assess HTPs in 2019, the estimated past 30-day use of HTPs was 1.6%, 1.4%, 0.7%, and 1.0% in 2019, 2020, 2021, and 2022, showing no increase since *IQOS* was authorized in late 2019.⁹

⁶ Birdsley J, Cornelius M, Jamal A, et al. (2023). Tobacco Product Use Among Middle and High School Students – National Youth Tobacco Survey, 2023. *Morbidity and Mortality Weekly Report*, 72(44), 1173-1182.

⁷ Dai, H. Heated tobacco product use and associated factors among U.S. youth, 2019. *Drug Alcohol Depend.* 2020;214:108150.

⁸ Czoli, CD; White, CM; Reid, JL, et al. Awareness and interest in *IQOS* heated tobacco products among youth in Canada, England and the USA. *Tob Control.* 2019;29(1):89-95.

⁹ Gentzke et al., Tobacco Product Use and Associated Factors Among Middle and High School Students - United States, 2021 *MMWR Morb Mortal Wkly Rep.*2020; 69(50): 1881-1888.

Confidentiality Statement

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris Products S.A.

Philip Morris Products S.A.	Confidential
2024 PMSS Report: <i>IQOS</i> devices & <i>HeatSticks</i>	Page 9 of 10
Annex 1: MRTP Use Behavior and Consumer Understanding and Perception	Version 1.0

Taken together, the most recent data from the UTUS and NYTS demonstrate low usage of heated tobacco products, including *IQOS* among underage individuals in the U.S. in 2023.

Table 2: UTUS 2023 to 2024 Estimates: Awareness, Ever Use, and Past 30-Day Use of *IQOS*

	Awareness		Ever <i>IQOS</i> Use		Past 30-Day <i>IQOS</i> Use	
	Unweighted <i>n</i>	Weighted % (95% CI)	Unweighted <i>n</i>	Weighted % (95% CI)	Unweighted <i>n</i>	Weighted % (95% CI)
Overall, <i>N</i> =4656, (13-20 Years)	255	5.47 (4.73, 6.32)	36	0.70 (0.47, 1.06)	8	0.21 (0.08, 0.52)
Youth, <i>N</i> =2658, (13-17 Years)	98	3.47 (2.79, 4.31)	10	0.42 (0.22, 0.80)	2	0.09 (0.02, 0.38)
Young Adults, <i>N</i> =1907, (18-20 Years)	157	9.41 (7.87, 11.21)	26	1.26 (0.80, 1.98)	6	0.44 (0.19, 0.99)

Sources: UTUS data collected from April 2023 to February 2024. Percentages are derived from weighted data. *N*'s are derived from unweighted data. Sample sizes may vary in each subgroup due to missing responses. Abbreviations: UTUS = Altria Client Services Underage Tobacco Use Survey; CI = Confidence Interval.

Confidentiality Statement

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris Products S.A.

Philip Morris Products S.A.	Confidential
2024 PMSS Report: <i>IQOS</i> devices & <i>HeatSticks</i>	Page 10 of 10
Annex 1: MRTP Use Behavior and Consumer Understanding and Perception	Version 1.0

5. CONCLUSIONS – MRTP USE BEHAVIOR AND CONSUMER UNDERSTANDING AND PERCEPTION

Evidence from the U.S. reveals no sales and suggests correspondingly low use of the *IQOS* system among legal age adult cigarette smokers. As the *IQOS* market reopens and adult cigarette smokers again become aware of the *IQOS* system as a reduced exposure tobacco option, we expect that adult *IQOS* uptake will increase.

Evidence continues to demonstrate that *IQOS* can benefit the health of the population as a whole by transitioning adult cigarette smokers away from cigarettes. Our previously submitted research has shown substantial switching (~40%) and smoking reduction (~60%) rates amongst adults who smoke and begin using the *IQOS* system. Importantly, there is little indication of youth and underage young adult use of *IQOS* at the time of this report.

6. ANNEXES

- a03- Research Analysis Report – Estimation of Awareness and Use of *IQOS* among Underage Individuals 13-20 Years of Age (UTUS Analysis Report for *IQOS* PMSS 2024.pdf)
- a04- Research Analysis Report – Estimation of Prevalence of *IQOS* Use (ATCT Analysis Report for *IQOS* PMSS 2024.pdf)

Confidentiality Statement

Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Philip Morris Products S.A.